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(54) Title: METHOD AND SYSTEM FOR PROVIDING GENOTYPE CLINICAL INFORMATION OVER A COMPUTER NETWORK

(57) Abstract: A system and method for securely providing personal clinical profile information to individuals over the Internet. The system and method provides for extracting a biological sample from an individual, extracting deoxyribonucleic acid (DNA) from the sample, analyzing the DNA to determine single nucleotide polymorphism (SNP) data, analyzing the SNP data, and securely providing access to the results of the analysis over the Internet.

METHOD AND SYSTEM FOR PROVIDING GENOTYPE CLINICAL INFORMATION OVER A COMPUTER NETWORK

FIELD OF THE INVENTION

The present invention broadly concerns a method and system for providing personal genotype clinical profile information, and more particularly concerns a method and system for securely providing such information to individuals over the Internet.

BACKGROUND OF THE INVENTION

Biomedical research is providing new insights into how a person's specific genetic make-up effect his or her susceptibility to disease. Much of this research is a result of the Human Genome Project (HGP). The HGP is being undertaken in laboratories around the world where scientists are determining specific genetic codes within human deoxyribonuclecic acid (DNA).

The study of genetic diversity at the molecular level is a rapidly growing field of biomedical science. With an increasing fraction of the human genome now determined, or sequenced, the degree and nature of this genetic diversity represents a richer field of scientific enquiry. One area of intense study is how some of the differences in DNA (called "polymorphisms") can effect a person's susceptibility to disease and/or response to drugs. Technology is available to measure individual DNA differences at the single nucleotide base level. Single nucleotide differences in DNA, known as "single nucleotide polymorphisms" ("SNPs"), are thought by many scientists to represent the most common form of genetic diversity. Technology is

available for detecting SNPs. This technology is being applied to the study of genetic differences in humans that can correlate to medically important aspects of a person. This field, as it applies to pharmaceuticals, is known as "Pharmacogenetics;" the study of the variations of effects of drugs caused by genetic variability of persons.

Practical consequences of Pharmacogenetics have been recognized for decades. Pharmacogenetic effects on a person include various undesirable reactions to administered drugs. As a consequence, it is common practice for medical practitioners to question patients as to whether they are allergic to penicillin or other antibiotics, prior to the administration of a drug. This procedure is practiced because some people are highly susceptible to severe adverse medical consequences in response to these compounds, which are drugs that a majority of the population responds to quite normally. With an increase in drug development and an increase in Pharmacogenetic research, the list of adverse medical reactions to various drugs in sub-populations is increasing.

The Journal of the American Medical Association has reported that adverse drug response (ADR) is responsible for up to 500,000 hospitalizations and 50,000 deaths per year. Yet, many ADR cases go unreported because they are not recognized, due to complexities inherent in the medical profession. For example, a patient who was admitted to a hospital for a serious medical condition and who later died from an adverse reaction to a drug administered to treat the condition, might be reported as dying from the original condition listed on the admissions report. Other circumstances that may have transpired during the hospitalization might not be reported.

Additionally, a growing number of medical professionals state that ADR represents a leading cause of hospitalization and death. Some scientists suspect that molecular irregularities caused by genetic differences can be the cause of many of these ADRs.

Another problem facing the healthcare industry is the rising costs of discovering and developing new drugs. New drugs can take from ten to fifteen years to reach the market and can cost from 100 to 500 million dollars to develop. At least half of this time and expense relate to the development phase of the drug, including clinical trials for preparation of a request for approval from the Food and Drug Administration (FDA). The process of clinical trials results in statistical analysis of a response or lack of response to selected dosed trial patients. Some of the doses are placebos that are known to have no intended medical effect. A trial drug that creates little or no difference in outcome, compared to the group that received the placebo, may be dropped from the development process. This is a common occurrence and is partly responsible for the time and expense taken to develop the drugs. With an increased understanding of the diversity in genes among people, scientists are investigating the effect of this diversity on patients' response to drugs. It is common for a drug to work in one group of people, but not function at all or insufficiently in a larger group of people; thus rendering the statistical analysis of the drug as not differing markedly from the placebo. In some cases, it is believed that differences in efficacy of a drug among people can be correlated to individual genetic differences. These differences might be in the gene that codes for an enzyme that metabolizes the drug to a useful molecular form in the body. In the absence of a correctly functioning enzyme, the person might not respond to the drug at all. However, this same person may respond to a drug of a similar molecular design which

did not require metabolization by the particular enzyme. Such information is highly valuable when developing a drug to work broadly, independent of genetic differences. For many drug therapies, it is not possible to find a drug suitable for everyone. In such cases, a genetic test might determine if the drug being considered for administration to a patient would be likely to be effective at treating the patient. The lack of efficacy of drugs in sub-populations is a problem that leads to wasted prescription expenses as well as delayed treatment. It is a common experience for people to have to return to their doctor with a complaint that the drug prescribed to them is either not working or is causing undesirable side effects. In many cases, the process eventually leads the person to a drug that works and does not cause significant side effects. In more severe cases, the delay in finding the appropriate treatment may change the course of the disease and could lead to a more severe disease or death of the person.

Many diseases have a slow onset and do not cause significant symptoms for years. The disease may eventually become established to cause the person to become aware of the disease and to seek medical advice and treatment. In other cases, a person shows symptoms of the disease too late to adequately treat the condition. In circumstances where the presence of a disease or predisposition to a disease can be determined prior to symptoms, and in such cases where adequate treatment exists, it may be practical for individuals to be given early advisories to take drugs prophylactically or proactively. Especially with inherited predispositions to disease, it may be possible to delay or completely avoid the onset of the most severe consequences of the disease by taking the appropriate medication years, if not decades, prior to there being significant symptoms. An increasing number of these predispositions are being found to correlate to specific

SNPs. As the number of such genetic variations are uncovered, it may be possible to create a list of drugs effective to delay or eliminate the onset of otherwise life-threatening conditions resulting from genetic variations. This can save total healthcare expenses, improve the quality of life for the patient, and increase revenue for specific drugs.

As more information regarding the causative relationships between polymorphisms in genes and health becomes available, patterns and clusters of SNPs are expected to be identified as significant. These clusters are known as Haplotypes and Genotypes and are helpful in reviewing the significance of groups of SNPs. In all of its forms, the study genetic variability is a matter of statistics and correlations. The exact molecular relationships between SNPs and the function or dysfunction of genes or the proteins they code are frequently not understood. Even when the molecular relationships are not understood, strong and reliable correlations can still be identified in many cases by sampling a large number of patients and recording accurately their medical histories including their response to drugs. Genotypes and Haplotypes are the lexicon of correlations between patterns of genetic variability and the medical condition and treatment response of patients.

Generally, privacy issues regarding an individual's genotype clinical profile information is of some significance, due to the predictive nature of the information. An individual seeking genetic testing for predisposition to diseases or various disorders, may receive test results that could be used to discriminate against the individual. For example, if test results are such that the individual has a predisposition to development of cancer such as breast cancer, then an insurance

company could use this information to deny insurance coverage. Additionally, a potential employer could use this information to decide against hiring an individual. Yet, this type of information is of some importance and use to many individuals interested in self healthcare management. Having this information and service available over a computer network, such as the Internet, allows for individuals all over the world to have access to genotype clinical profile information and services. Even though the Internet is a public communication channel, which is venerable to attacks on privacy and misdirection of confidential information, current Internet security technology makes it possible to securely offer genotype clinical information and services over a computer network.

Numerous types of medical data collection, storage, and display systems are available for use by individuals seeking medical information regarding their health. Examples include the system described in U.S. Pat. No. 5,876,926 entitled "Method, Apparatus And System For Verification Of Human Medical Data", issued to Beecham. This patent discloses a method and system for taking a sample from a patient, at a sample collection station, and providing test results performed on the sample over a telephone system or a computer display system.

Another example is described in U.S. Pat. No. 5,612,870 entitled "System For Tracking Secure Medical Test Cards", issued to Welner. This patent is directed to a method and an apparatus for tracking information associated with a plurality of medical test cards, to prevent counterfeiting or unauthorized manufacturing of the test cards and to maintain anonymity of clients.

Despite the existence of these systems, no one has conceived a method and system where a client takes a biological sample of himself or herself at a location of their choice, sends the biological sample to a laboratory for single nucleotide polymorphisms (SNP) analysis, and securely accesses the results of the analysis over a computer network, such as the Internet.

Until now, individuals have not had access to a system and method that provides genotype clinical profile information and related testing services. Accordingly, there is a need for a system and method that conveniently and securely provides personal genotype clinical profile information and services.

SUMMARY OF THE INVENTION

The present invention satisfies the above described needs by providing a secure network-accessible personal genotype clinical profile system and method. In the personal genotype clinical profile method of the invention, a client submits a biological sample containing the client's DNA to a laboratory, and thereafter is provided secure access over a computer network, such as the Internet, to genotype clinical profile information that correlates to the client's DNA. In particular, the client extracts a biological sample which contains the client's DNA (some e.gs. blood, hair, skin, finger nail clipping, saliva) using a biological sampling kit which can be used at home. The biological sample is sent to a laboratory where DNA is extracted from the sample. The DNA is analyzed to determine single nucleotide polymorphism (SNP) data. The SNP data is then analyzed for genotype clinical profile information, such as an adverse response to certain drugs or a predisposition to certain diseases. The genotype clinical profile information for the client is

securely stored in a database that is accessible over a computer network such as the Internet. The client is provided with a user name and a password to permit only the client to access his or her genotype clinical profile information. The client can permit others, such as a physician, to access all or part of the client's genotype clinical profile information over the computer network.

In the personal genotype clinical profile system of the invention, a biological sampling kit provides a means for extracting a biological sample form a client. The biological sample is sent to a laboratory where DNA is extracted from the sample and the DNA is analyzed for single nucleotide polymorphism (SNP) data. The SNP data is entered into a computer system where it is analyzed for genotype clinical profile information, such as an adverse response to certain drugs or a predisposition to certain diseases. The results of the analysis are securely stored in a database and are made available to the client over a computer network, such as the Internet. Although the Internet is used in the preferred embodiment, the invention is applicable to any computer network topology where secure transactions between interconnected computers are provided. Using a personal computer system that is interconnected to the Internet, the client remotely accesses a server computer system that is coupled to the database. Using a user name and password, the client can access his or her genotype clinical profile information securely stored in the database.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a block diagram of a preferred personal genotype clinical profile system.

FIG. 2 is a flowchart outlining the preferred method for accessing the system.

FIG. 3 illustrates a preferred home Web page.

FIG. 4 illustrates a preferred user name and password Web page.

FIG. 5 is a flowchart outlining the preferred method for generating and receiving broadly grouped genotype clinical information.

FIGS. 6-7 are flowcharts outlining the preferred method for generating and receiving personal genotype clinical profile information.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS OF THE INVENTION

A preferred embodiment of the present invention is directed to a secure network-accessible personal genotype clinical profile system and method. The system and method is configured such that a client can submit a biological sample which contains his or her DNA to a laboratory where single nucleotide polymorphism (SNP) analysis is performed on the sample and correlated to genotype clinical information, which is made available to the client over the World Wide Web.

A block diagram of the overall preferred system architecture of the secure network-accessible personal genotype clinical profile system formed in accordance with the present invention is illustrated in FIG. 1. The personal genotype clinical profile system includes: a server computer system 2, a plurality of client computer systems 4, a database server system 6, a SNP computer system 8, a SNP database system 10, a general information database server system 12, the Internet 14, a laboratory 16, an optical detector 18, and an e-mail server system 20.

The Internet 14 is a global network of interrelated computer networks allowing

interchange of information between network accessible computers. Each client computer system 4 and the server computer system 2 can communicate with each other by communication protocols well known in the art as applied to the particular network being implemented. Thus, for the preferred embodiment Internet connections, the TCP/IP protocol suite well known in the art will be implemented by each party to the transaction as described herein.

Each of the client computer systems 4, designated as Client 1, Client 2, ... Client n, in FIG. 1, is interconnected to the Internet 14 by various means known in the art, such as a dial-up modem connection to an Internet Service Provider (ISP) or a direct connection to a network that is connected to the Internet 14. Typically, the client computer system 4 is a computer (an e.g. personal computer) in a home or a business environment that accesses the Internet 14 through a commercially-available browser client software package. Typical browser interfaces include a window frame which encompasses a control region and a viewing region. The control region typically includes page controls which allow users to navigate between various pages of data provided by the server computer system 2. The viewing region typically includes a viewing area which provides a region into which text, hypertext links, and graphics are displayed to the user for examination.

The server computer system 2 is also connected to the Internet 14 as shown in FIG. 1, and provides clients access to a personal genotype clinical profile service Web site. The server computer system 2 includes computer hardware and software to serve up Web pages from the Web site. The server computer system 2 manages the communications protocols and houses the

pages and related software required to create the Web site on the Internet 14. The server computer system 2 also provides data and software that is accessible to the various clients which are in communication with the server computer system 2. The server computer system 2 provides services such as searching for information and sending it back to the client computer system 4, such as when the database server system 6 or the general information database server system 12 at the Web site is queried or delivering Web pages. Typically, the browser on the client computer system 4 sends the server computer system 2 a request for a specific Web page. The server computer system 2 processes that request and sends an answer back to the browser, most often in the form of a Web page. The construction and operation of the server computer system 2 will be well known to those skilled in the art. In particular, the server computer system 2 will be configured to provide data that is compatible with browser software such as that used to view data on the World Wide Web. In addition, the data provided by the server computer system 2 will be in the form of pages of data that can be examined using conventional browser software. The server computer system 2 runs a Web server program that allows Web pages (in HTML format) to be accessed by clients. The server computer system 2 also executes other programs and subroutines as required to host the Web site.

Also running on the server computer system 2 are gateway programs used to provide access from the Web to the database server system 6 and the general information database server 12. The Common Gateway Interface (CGI) specification is implemented to extend the services and capabilities of the server system 2 to the database server system 6 and the general information database server 12. CGI scripts are used in large part to produce from non-Hypertext Transfer

Protocol (HTTP) objects, HTTP objects that a Web client can render, and also produce from HTTP objects, non-HTTP objects to be passed on to another program or separate server, such as the database server system 6 and the general information database server 12. The construction and operation of the database server system 6 and the general information database server 12 will be well known to those skilled in the art. The server computer system 2 passes requests to run CGI scripts to the CGI applications. These scripts run external programs, such as database lookup or interactive forms processing. The server computer system 2 sends the script to the application via CGI and communicates the results of the script back to the browser on the client computer system 4. For example, the client fills out a form on a Web page to register to use the Web site and then later receives a notification of registration. The CGI script takes the information the client filled in on the form and stores the information in the database server system 6, and then sends the notification of the registration to the client's browser.

The database server system 6 includes computer hardware and software for communicating with the server computer system 2, storing general genotype clinical information retrieved from the general information database server system 12, and storing a client's relevant genotype clinical profile information from the SNP computer system 8, all in association with the client's user name and passwords. The general information database server system 12 includes computer hardware and software for allowing a client to perform field and full text searches, and store the information in the database server system 6. The construction and operation of the database server system 6, and the general information database server system 12 will be well known to those skilled in the art.

The preferred e-mail server system 20 is coupled to the server computer system 2 via a network and can receive and deliver e-mail messages addressed to users through the Internet. The e-mail server system 20 includes computer hardware and software capable of receiving and delivering e-mail messages over a computer network. The e-mail server system 20 communicates the e-mail to other servers on the Internet using the simple mail transfer protocol (SMTP). The e-mail is read from the server using a post office protocol (POP), such as POP3.
The e-mail server 20 is structured and functions following a standard format generally known and available within the art.

Security and privacy issues regarding the transfer of financial information, passwords, and healthcare information over the Internet 12 is addressed by utilizing an asymmetric cryptography system. The preferred system is the Rivest - Shamir - Adelman algorithm (RSA) that is resident in the server computer system 2. It will be further appreciated by those skilled in the art that various security measurers can be implemented in accordance with the present invention to provide protection for data and the general operating environment at the client and server computer systems.

The laboratory 16 is preferably structured to receive a biological sample kit from the client, extract the client's DNA from the sample, and analyze the DNA to determine single nucleotide polymorphism (SNP) data. The extraction of the DNA from the biological sample and the analysis of the DNA for SNP data, may be accomplished by various means known within the art. Preferably, the laboratory 16 also includes the SNP computer system 8, the optical detector

18, and the SNP database system 10, which stores genotype clinical information relevant to patient healthcare. The SNP computer system 8 includes computer hardware and software for controlling and communicating with the optical detector 18, and to control and communicate with the SNP database system 10 and the database server system 6. The optical detector 18 produces SNP data for use in the SNP computer system. The SNP database system 10 includes computer hardware and software for communicating with the SNP computer system 8. The SNP computer system 8 includes a correlation algorithm that analyzes the SNP data. The correlation algorithm searches through the data stored in the SNP database system 10 for genotype clinical profile information relevant to the client's SNP data. The relevant genotype clinical profile information accumulated by the correlation algorithm is stored, as a report, in the database server system 6, under the appropriate client user name. The detection of the SNP data and the correlation of the SNP data to relevant genotype clinical profile information can be accomplished by various means known within the art. An example of one such means is discussed in U.S. Pat. No. 5,762,876 to Lincoln et al. entitled "AUTOMATIC GENOTYPE DETERMINATION" which has been incorporated herein in its entirety by reference.

Using his or her client computer system 4, the client can retrieve his or her genotype clinical profile information by accessing the server computer system 2, which is coupled to the database server system 6. The database server system 6 stores the genotype clinical profile information in the form of a report, under a user name chosen by the client, and is only accessible by submitting a correct user name and password.

In providing a secure network-accessible personal genotype clinical profile system, as described in connection with FIG. 1, the system preferably executes several distinct modules or processes. These processes include a client sending a biological sample to a laboratory for SNP analysis and providing access to the results of the analysis over the Internet 14. The steps associated with these processes are described in connection with FIGS. 2-7.

FIGS. 2-7 show flow charts that illustrate a preferred embodiment of the invention. Referring in particular to FIG. 2, a client, using the client computer system 4 and a commercially available Internet browser software located within the client's computer system 4, accesses the Web site that hosts the personal genotype clinical profile service (step 50). The client achieves this by entering a uniform resource locator (URL) associated with the IP address of the server computer 2. The client can be an individual seeking genotype clinical profile information; a physician seeking a patient's genotype clinical profile information; or a drug company interested in receiving genotype clinical information for use in medical research. In response, the server computer 2 transmits back to the client browser embedded Web pages for display on the client's computer system 4, such as the home Web page illustrated in FIG. 3, that provides links to genotype clinical information, services, and items (step 52). Once the client has found a desired item, information, or service, which will be displayed in hypertext markup language (HTML) format on the client's Web page, then the client clicks on an embedded control associated with the desired item or service (step 54). Such options can include subscribing to the personal genotype clinical profile service or accessing general genotype clinical information.

Once an option on the home Web page is selected, a user name and password window is displayed on the client's browser, as illustrated in FIG. 4. If the client has previously used the Web site, then he or she would have already registered with the site and established a user name and password. Having already registered with the site, the client can simply enter his or her user name and password, that were selected during the registration process, enter them into the Web page fields, and proceed to access the Web site, step 56 of FIG. 2. If the client has not previously registered with the Web site, then the client can return to the home Web page and click an embedded Web page control associated with registering with the Web site. The client must register with the Web site before he or she can access the Web site features. To register with the Web site, the client opens an account resident in the server computer system 2 by clicking on an associated Web page control and by following instructions listed on the Web page (step 58). A typical Web page screen for opening an account includes fields for client name, postal address, e-mail address, and user name and password. The client selects a user name and password and the server computer system 2 processes the information following a standard format generally known and available within the art.

Referring in particular to FIG. 5, once the client has registered with the Web site, he or she can chose to access payment or non-payment services. Nonpayment services can be accessed by clicking an associated Web page control and may include access to genotype clinical information, journals, and/or other types of data and, publications, and services (step 60). By clicking an embedded Web page control associated with a particular Web site feature, a number of medical and medical related categories and subcategories are at the client's dispense for obtaining medical

information relating to variability in human conditions, such as information sets designed for specific broadly grouped Genotypes and Halotypes. A client interested in receiving this healthcare information may answer a questionnaire relating to the client's health information, such as medical history, ancestry, blood type, family medical history and other various information (step 62). The questionnaire is displayed in a Web page where the client can insert information into Web page fields and send the information to the server computer system 2, by following a standard format and process generally known and available within the art. After submitting the questionnaire, the client can click a Web page control associated with requesting the health information in the questionnaire to be correlated to genotype clinical profile information that is stored in the SNP database system 10 (step 64). The health information is entered into the SNP computer system 8, where it is applied to the correlation algorithm that searches the SNP database system 10 for genotype clinical profile information relevant to the client's health information listed in the questionnaire. The relevant genotype clinical profile information accumulated by the correlation algorithm is stored, as a report, in the database server system 6, under the appropriate client user name (step 66). The client can later retrieve the relevant genotype clinical profile information, that was acquired from the correlation process, by accessing the server computer system 2 using his or her client computer system 4 and Web browser (step 68).

Referring in particular to FIGS. 6 and 7, the client is able to search through the general information database server system 12 for relevant health information. The clients are electronically linked to the medical information relating to variability in human conditions, so that the information can be collected, processed, stored, and transmitted to the client or a third party

upon request. The client can also be linked, via a Web page, to sites with a more detailed description of various medical conditions and recent discoveries to treatment and prognosis.

Additionally, the client can select services requiring payment, which can be accessed after filling out Web page fields requiring credit card information, such as credit card name, name on the credit card, credit card number and expiration date (step 70). One such service available to the client can be subscribing to the personal genotype clinical profile service. In addition to filling out the medical questionnaire described above, this service requires the client to submit a biological sample (an e.g. blood) from himself or herself and to send it to the laboratory 16 for SNP analysis and correlation analysis. Once the client is registered with the Web site and has filled out the medical questionnaire, the client can elect to create a personal genotype clinical profile of himself or herself, by clicking an associated Web page control (step 72). Additionally, the client fills in Web page fields requiring the client to provide a second password that can be used by the client to access the client's personal genotype clinical profile information that can be stored in the secure database server system 6 (step 74). The second password is created following a standard format generally known and available within the art. The client can then request that a biological sampling kit be sent to the client's postal address, which was provided when the client opened his or her account (step 76). In addition to electronically ordering the kit, the client may purchase the kit at a pharmacy or other retail outlet. The client can also fill out Web page fields requiring his or her credit card information, such as credit card name, name on the credit card, credit card number, and credit card expiration date, so that the client may be charged a fee for the kit. The biological sampling kit contains a specimen container, such as a test card, a test tube, a

lance, or a swab, for containing a biological sample or specimen for transportation to the laboratory 14. The biological sample can be anything containing DNA, such as blood, hair, sputum, saliva, stool, urine, semen, or saliva. The biological sample can be from a mammal, such as humans, dogs, mice, cows, horses, and a like. The sampling kit preferably includes a specimen test card that contains a space for the client to print his or her user name on the card, a space for depositing a drop of blood, and a lance to safely obtain blood from the client.

The client deposits a sample of blood on the test card and sends (an e.g. by mail) the specimen test card to the laboratory 14 (step 78). At the laboratory 14, the client's DNA is extracted from the blood sample that was deposited on the specimen test card (step 80). The client's DNA is then analyzed to determine single nucleotide polymorphism (SNP) data (step 82). The SNP data is entered into the SNP computer system 8, where it is applied to a correlation algorithm that searches the SNP database system 10 for genotype clinical profile information relevant to the client's SNP data. The relevant genotype clinical profile information accumulated by the correlation algorithm is stored in the database server system 6, under the appropriate client user name (step 84). Such information can be an adverse response to certain drugs, lack of efficacy, and a predisposition to certain diseases. The client's genotype clinical profile information is stored as a report in the SNP database system 10 that is accessible over the Internet 12 through the Web site.

After the client submits his or her biological sample, the client can retrieve his or her genotype clinical profile information by accessing the Web site. After accessing the Web site,

using the client's browser, the client logs on to the site by submitting his or her user name and password to verify that the client has registered with the Web site and is entitled to use the Web site features (step 86). To determine if the client's personal genotype clinical profile information is available or has been updated, the client clicks an associated Web page control and a Web page is presented to the client indicating such information. If the client's personal genotype information is available, has been updated, or the client wants to review the information in his or her file, then the client clicks on a Web page control associated with accessing this information (step 88). After clicking the Web page control, but before the requested Web page is displayed, a Web page presents the client with a user name field and a second password field, which the client must accurately fill out to gain access to his or her personal genotype clinical profile information file (step 90). If the user name and password is correct then the Web page containing the client's personal genotype information is displayed on the client's browser (step 92). This information is stored in the database server system 6 and can be viewed on the clients's browser in the form of reports and advice as it relates to the growing set of correlations relating to genotype healthcare information, such as adverse drug response, lack of efficacy, and proactive drug treatment. The reports are preferably in a form that conform to industry standards of the Clinical Reference Laboratory.

The client also has the option of forwarding his or her general or personal genotype clinical profile information or subset of this information to third parties, such as physicians, healthcare providers, or family members, who have access to the Internet. The client can select and remove text from a Web page displaying such information, using standard controls available

on the client's browser. The client can then click a Web page control associated with forwarding information to a third party, which results in a standard e-mail service being displayed on the browser. The e-mail server 20 is structured and functions following a standard format generally known and available within the art. Using standard browser controls, the client inserts the selected text into an e-mail text window and enters an e-mail address to which the client would like to have the e-mail sent. The client then clicks a button associated with sending the e-mail (step 94).

It will be apparent to those skilled in the art that various modifications and variations can be made in the system and method of the present invention without departing from the spirit and scope of the invention. Thus, it is intended that the present invention cover all modifications and variations of the invention within the scope of the appended claims.

What is claimed is:

1. A method for providing a secure network-accessible personal genotype clinical profile service comprising the steps:

(a) extracting a biological sample;

(b) sending the biological sample to a laboratory where it is analyzed to determine single nucleotide polymorphism (SNP) data;

(c) correlating, using a SNP computer, the SNP data to relevant genotype clinical profile information;

(d) storing the relevant genotype clinical profile information in a database server system; and

(e) accessing, using a client computer system, the relevant genotype clinical profile information over a computer network.

2. The method of claim 1, wherein the biological sample is from a human.

3. The method of claim 1, wherein the computer network is the Internet.

4. The method of claim 1, further comprising the step of forwarding, using an e-mail server system, all or parts of the relevant genotype clinical profile information to an individual having access to the Internet.

5. A method of claim 1, wherein the relevant genotype clinical profile

information relates to adverse drug response, and/or lack of efficacy, and/or proactive drug treatment.

6. A method for providing a secure network-accessible personal genotype clinical profile service comprising the steps:

(a) receiving a biological sample;

(b) analyzing the sample to determine single nucleotide polymorphism (SNP) data;

(c) correlating, using a SNP computer system, the SNP data to relevant genotype clinical profile information;

(d) storing the relevant genotype clinical profile information in a database server system; and

(e) providing access, using a server computer system, to the relevant genotype clinical profile information over a computer network.

7. The method of claim 6, wherein the biological sample is from a human.

8. The method of claim 6, wherein the computer network is the Internet.

9. The method of claim 6, further comprising the step of forwarding, using an e-mail server system, all or parts of the relevant genotype clinical profile information to an individual having Internet e-mail service.

10. A method of claim 6, wherein the relevant genotype clinical profile information relates to adverse drug response, and/or lack of efficacy, and/or proactive drug treatment.

11. A method for providing a secure network-accessible personal genotype clinical profile service comprising the steps:

(a) extracting a biological sample;

(b) extracting DNA from the sample;

(c) analyzing the DNA to determine single nucleotide polymorphism (SNP) data;

(d) correlating, using a SNP computer system, the SNP data to relevant genotype clinical profile information;

(e) storing the relevant genotype clinical profile information in a database server system; and

(f) providing access, using a server computer system, to the relevant genotype clinical profile information over a computer network.

12. The method of claim 11, wherein the biological sample is from a human.

13. The method of claim 11, wherein the computer network is the Internet.

14. The method of claim 11, further comprising the step of forwarding, using an

e-mail server system, all or parts of the relevant genotype clinical profile information to an individual having Internet e-mail service.

15. A method of claim 11, wherein the relevant genotype clinical profile information relates to adverse drug response, and/or lack of efficacy, and/or proactive drug treatment.

16. A method for providing a secure network-accessible personal genotype clinical profile service comprising the steps:

(a) extracting a biological sample;

(b) analyzing the sample to determine single nucleotide polymorphism (SNP) data;

(c) correlating, using a SNP computer system, the SNP data to relevant genotype clinical profile information;

(d) storing the relevant genotype clinical profile information in a database server system; and

(e) providing access, using a server computer system, to the relevant genotype clinical profile information over a computer network.

17. The method of claim 16, wherein the biological sample is from a human.

18. The method of claim 16, wherein the computer network is the Internet.

19. The method of claim 16, further comprising the step of forwarding, using an e-mail server system, all or parts of the relevant genotype clinical profile information to an individual having Internet e-mail service.

20. A method of claim 16, wherein the relevant genotype clinical profile information relates to adverse drug response, and/or lack of efficacy, and/or proactive drug treatment.

21. A secure network-accessible personal genotype clinical profile system comprising:

a laboratory for receiving a biological sample and analyzing the biological sample for SNP data;

a SNP database for storing genotype clinical profile information;

a SNP computer system, coupled to the SNP database, the SNP computer system having a correlation algorithm for correlating the SNP data to relevant genotype clinical profile information stored within the SNP database;

a database server system, coupled to the SNP computer system, for storing the relevant genotype clinical profile information; and

a server computer system, coupled to the database server system, for providing computer network access to information stored in the database server system.

22. A system as in claim 21, further comprising an optical detector, coupled to

the SNP computer system, to produce the SNP data for entry into the SNP computer system.

23. A system as in claim 21, further comprising a biological sampling kit for extracting a biological sample.

24. A system as in claim 21, wherein the computer network access is over the Internet.

25. A method comprising the steps of:

(a) providing, to a computer, SNP data;

(b) correlating, using the computer, the SNP data to relevant genotype clinical profile information;

(c) transmitting, using a computer, a request for genotype clinical profile information that correlates to the SNP data; and

(d) receiving, using a computer, relevant genotype clinical information.

26. A method of claim 25, wherein providing the SNP data includes answering a questionnaire related to a client's health.

27. A method of claim 25, wherein the questionnaire includes medical information that relates to the individual's medical history, ancestry, and/or blood type.

28. A method comprising the steps of:

(a) receiving, using a SNP computer system, SNP data;

(b) correlating, using the SNP computer system, the SNP data to relevant genotype clinical profile information; and

(c) sending, using a server computer system, the relevant genotype clinical profile information;

29. A system comprising:

a SNP database system having embedded therein information relating to genotype clinical profile information;

a SNP computer system in communication with the SNP database system, the SNP computer system configured to:

receive SNP data;

correlate the SNP data to relevant genotype clinical profile information stored within the SNP database system;

make available the relevant genotype clinical profile information on a database server system; and

a server computer system in communication with the database server system, the server computer system configured to:

provide secure network access to the relevant genotype clinical profile information.

30. A secure network-based genotype clinical profile information system, comprising:

(a) at least one client computer system for operation by a client desiring to receive genotype clinical profile information;

(b) at least one server computer system with access to a general information database server system having genotype clinical profile information stored within;

the client computer, and the server computer being interconnected by a computer network;

the server computer being programmed to send a questionnaire to the client computer where the client computer is programmed to receive the questionnaire so that the client can answer the questionnaire and send it to the server computer;

the server computer being programmed to receive an answered questionnaire containing health information and to cause the health information to be correlated to relevant genotype clinical profile information where an SNP computer system identifies relevant genotype clinical profile information that correlates to the health information; and

the server computer being programmed to provide network access to the relevant genotype clinical profile information that correlates to the healthcare information.

31. A secure network-based genotype clinical profile information system, comprising:

means for analyzing a biological sample for SNP data;

means for correlating the SNP data to relevant genotype clinical profile information; and

means for providing access to the relevant genotype clinical profile information over a computer network.

FIG. 1.

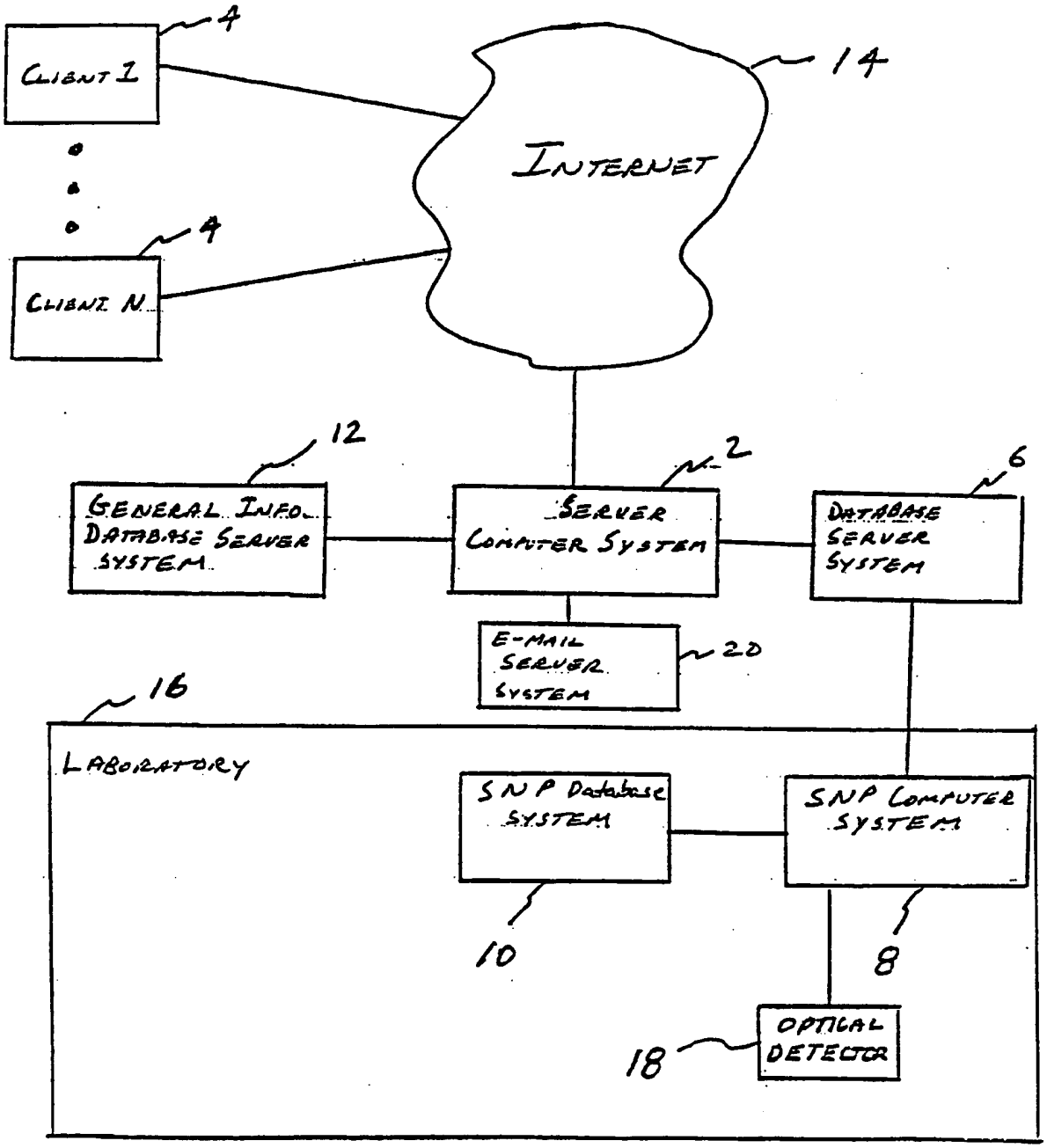

CLIENT 1
4
CLIENT N
4
INTERNET
14
GENERAL INFO. DATABASE SERVER SYSTEM
12
SERVER COMPUTER SYSTEM
2
DATABASE SERVER SYSTEM
6
E-MAIL SERVER SYSTEM
20
16
LABORATORY
SNP Database SYSTEM
SNP COMPUTER SYSTEM
10
8
OPTICAL DETECTOR
18

FIG. 2

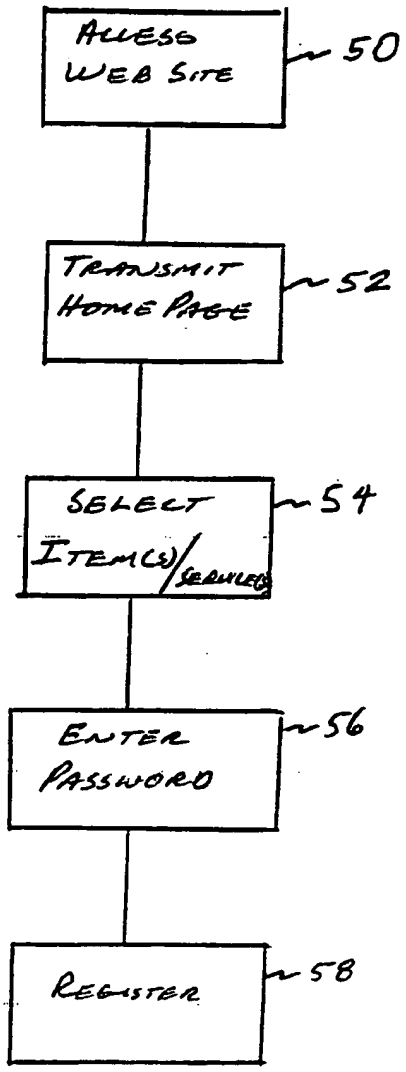

ACCESS WEB SITE
50
TRANSMIT HOME PAGE
52
SELECT ITEM(S)/SERVICE(S)
54
ENTER PASSWORD
56
REGISTER
58

FIG.3

About Us | Pharmacogenetics | Your Health | GeneAlert

Biomedical research is providing new insights into how an individual's specific genetic make-up effect their susceptibility to disease. Much of this research is a byproduct of the Human Genome Project (HGP). The HGP is being undertaken in laboratories around the world where scientists are determining the specific genetic code comprised of DNA. The technology for determining this code or sequence of DNA has made dramatic progress during the 1990s.

FIG. 4

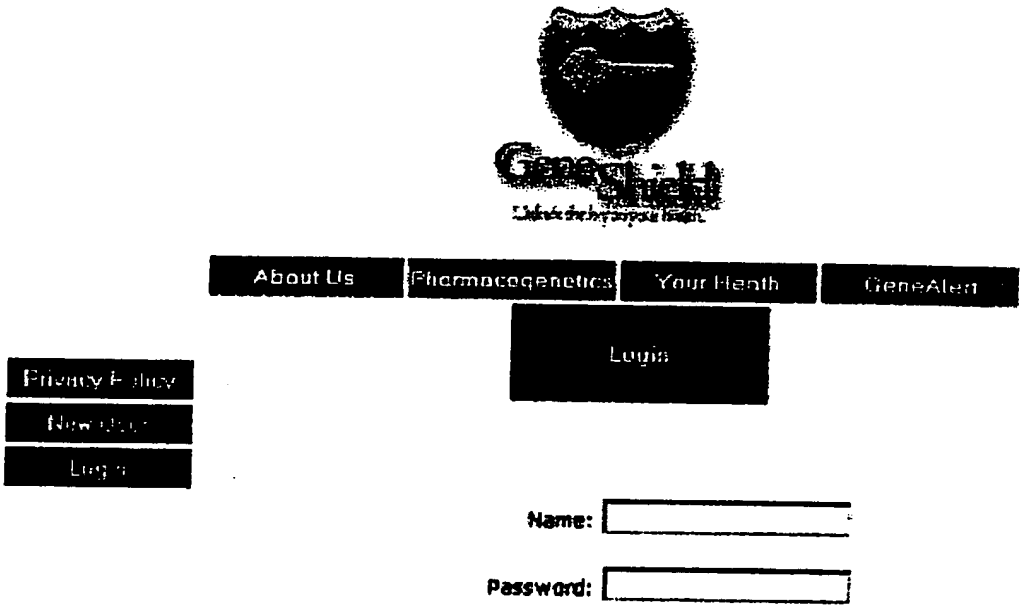

About Us
Pharmacogenetics
Your Heath
GeneAlert
Login
Name:
Password:

FIG. 5

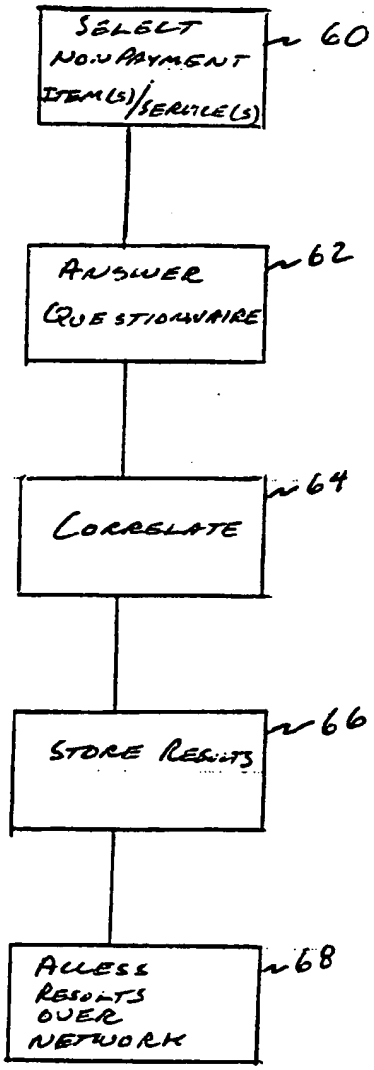

SELECT NON-PAYMENT ITEM(S)/SERVICE(S)
60
ANSWER QUESTIONNAIRE
62
CORRELATE
64
STORE RESULTS
66
ACCESS RESULTS OVER NETWORK
68

FIG. 6

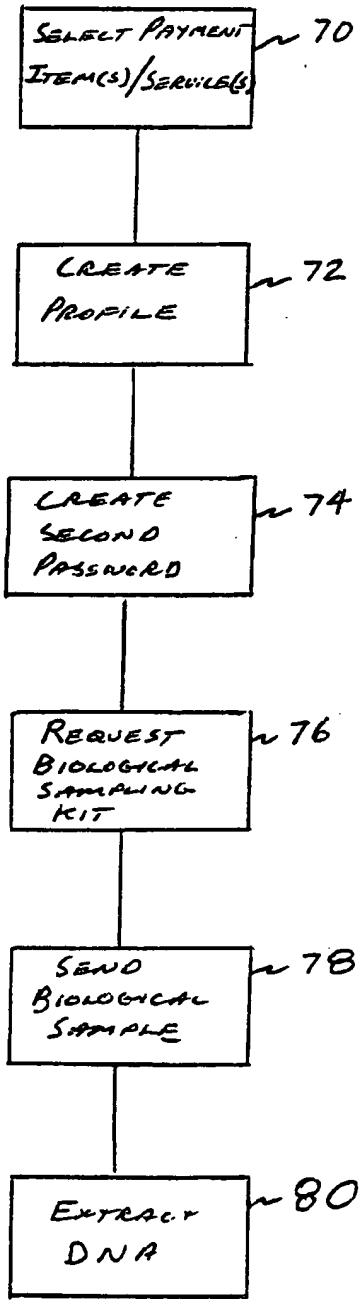
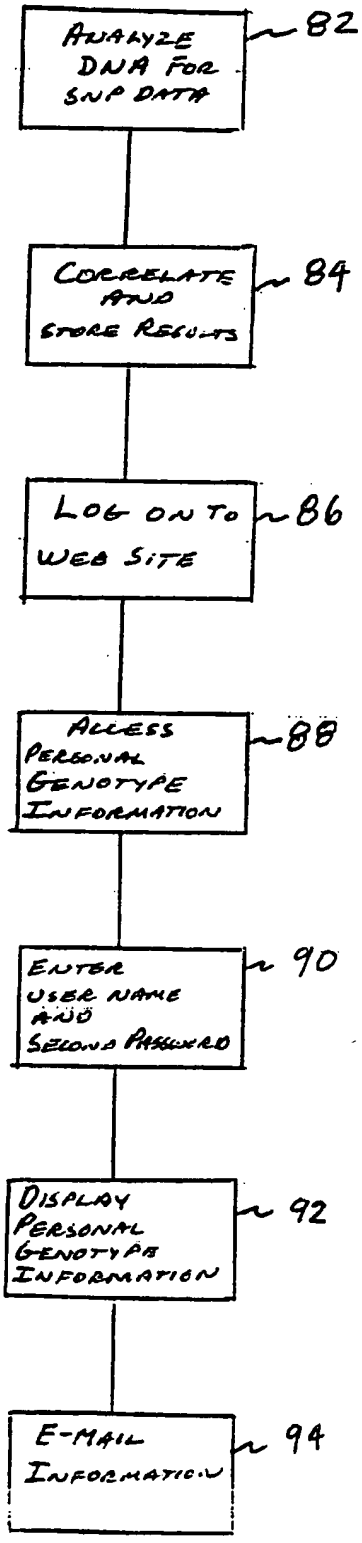

SELECT PAYMENT ITEM(S)/SERVICE(S)
70
CREATE PROFILE
72
CREATE SECOND PASSWORD
74
REQUEST BIOLOGICAL SAMPLING KIT
76
SEND BIOLOGICAL SAMPLE
78
EXTRACT DNA
80

FIG. 7


ANALYZE DNA FOR SNP DATA
82
CORRELATE AND STORE RESULTS
84
LOG ON TO WEB SITE
86
ACCESS PERSONAL GENOTYPE INFORMATION
88
ENTER USER NAME AND SECOND PASSWORD
90
DISPLAY PERSONAL GENOTYPE INFORMATION
92
E-MAIL INFORMATION
94

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